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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,849	01/13/2006	Dorian Bevec	ARTHP1116US	2217
23623 7590 02/28/2008 AMIN, TUROCY & CALVIN, LLP 1900 EAST 9TH STREET, NATIONAL CITY CENTER 24TH FLOOR, CLEVELAND, OH 44114			EXAMINER BRADLEY, CHRISTINA	
			ART UNIT 1654	PAPER NUMBER
			NOTIFICATION DATE 02/28/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/564,849	Applicant(s) BEVEC, DORIAN	
	Examiner CHRISTINA BRADLEY	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 1-18 are pending. Applicant's elected SEQ ID NO: 4 and idiopathic pulmonary fibrosis in the reply filed on 4/2/2007 with traverse.

Claim Objections

2. Claims 1-18 objected to because of several grammatical errors that appear throughout the claim listing. For example, in claim 1 “associated to” should be “associated with”. In claim 2, “amino acid sequence” should be plural. In claim 3, “peptide or polypeptide” is singular but the verb “having” is plural. Appropriate correction is required.

Claim Rejections - 35 USC § 112/101

3. The rejection of claims 1-18 under 35 USC 112/101 is withdrawn in light of the amendment to the claims filed 12/13/2007.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first

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paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and are as follows:

The Nature of the Invention

6. The invention is drawn to a method of inhibiting maturation of dendritic cells for the treatment of a pulmonary disease which is directly or indirectly associated with idiopathic pulmonary disease, hypersensitive pneumonia or diffused panbronchitis comprising administering a peptide comprising SEQ ID NO: 4.

The State of the Prior Art and its Predictability or Unpredictability

7. Todate *et al.* (*Am. J. Resp. Crit. Care Med.*, **2000**, 162, 148-53) demonstrated that the number of dendritic cells and their phenotypic maturation in the bronchiolar epithelium and submucosal tissues of patients with diffused panbronchitis was significantly higher than in control subjects with normal lungs. These results suggest that accumulated dendritic cells may play an important role in the mucosal immune response against inhaled pathogens through their potent antigen-presenting function in patients with diffused panbronchitis. Todate *et al.* do not teach or suggest that inhibitors of dendritic cell maturation can be used to treat diffused panbronchitis.

8. The prior art does not teach or suggest a relationship between the inhibition of dendritic cell maturation and the treatment of idiopathic pulmonary disease or hypersensitive pneumonia nor does it teach or suggest the use of peptides comprising SEQ ID NO: 4 to treat these conditions.

The Relative Skill of Those in the Art

9. The relative skill of those in the art is high.

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The breadth of the claims

10. The scope of the claims includes the treatment of diseases directly or indirectly associated with idiopathic pulmonary disease, hypersensitive pneumonia or diffused panbronchitis. The specification fails to define diseases that are directly or indirectly associated with these three conditions.

The Amount of Direction or Guidance Presented and the Presence of Working Examples

11. The specification presents data establishing that peptides comprising SEQ ID NO: 4 can inhibit the maturation of dendritic cells *in vitro*. The specification fails to establish a relationship between this property and the treatment of idiopathic pulmonary disease, hypersensitive pneumonia and diffused panbronchitis. The specification does not include working examples of SEQ ID NO: 4 activity *in vivo* or in art-recognized models of idiopathic pulmonary disease, hypersensitive pneumonia or diffused panbronchitis. In addition, the specification fails to identify diseases and conditions associated with idiopathic pulmonary disease, hypersensitive pneumonia and diffused panbronchitis as well as guidance on how to identify such diseases and conditions.

The Quantity of Experimentation Necessary

12. Considering the factors above, the skilled artisan would be burdened with undue experimentation in determining if one of the claimed peptides would be effective at treating idiopathic pulmonary disease, hypersensitive pneumonia or diffused panbronchitis. The skilled artisan would be burdened with testing the peptides in animal models of these conditions. In addition, the skilled artisan would be burdened with undue experimentation in identifying other diseases that may be treated by the same peptide. When the above factors are weighed, it is the

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examiner's position that one skilled in the art could not practice the invention without undue experimentation.

13. Claims 1-8 and 12-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. The invention is drawn to a method of inhibiting maturation of dendritic cells for the treatment of a pulmonary disease which is directly or indirectly associated with idiopathic pulmonary disease, hypersensitive pneumonia or diffused panbronchitis comprising administering a peptide comprising SEQ ID NO: 4. The specification fails to define diseases that are directly or indirectly associated with these three conditions. As a result, the scope of diseases to be treated in the claimed invention is indefinite.

15. In claim 2, the use of the semicolon without a conjunction renders the claim indefinite. Does the polypeptide contain SEQ ID NOs: 14 and 13 or SEQ ID NOs: 14 or 13?

16. In claim 6, there is a lack of antecedent basis for X^1 - X^{22} due to the use of the singular verb to be.

Claim Rejections - 35 USC § 102

17. The rejection of claims 1-18 under 35 U.S.C. 102(b) as being anticipated by Block (WO 02/43746) is withdrawn in light of the amendments to the claims filed 12/13/2007.

Double Patenting

18. The rejection of claims 1-18 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/501,660 and

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claims 1-10 of copending Application No. 10/517,125 is withdrawn in light of the amendments to the claims filed 12/13/2007.

Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday, Tuesday and Thursday, 8:00 A.M. to 5:30 P.M.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

/Christina Marchetti Bradley/
Examiner, Art Unit 1654